

National Milk Producers Federation

National Milk Producers Federation • 2101 Wilson Blvd., Arlington, VA 22201 • 703-243-6111 FAX 703-841-9328

Agri-Mark, Inc.
Arkansas Dairy Cooperative Association
Associated Milk Producers, Inc.
California Dairies, Inc.
Cass-Clay Creamery, Inc.
Continental Dairy Products, Inc.
Cooperative Milk Producers Assn.
Dairy Farmers of America, Inc.
Dairymen's Marketing Cooperative, Inc.
Dairylea Cooperative Inc.
Ellsworth Cooperative Creamery
Farmers Cooperative Creamery
First District Association
Foremost Farms USA
Just Jersey Cooperative, Inc.
Land O'Lakes, Inc.
Lone Star Milk Producers, Inc.
Manitowoc Milk Producers Coop.
MD & VA Milk Producers Cooperative Association, Inc.
Michigan Milk Producers Assn.
Mid-West Dairymen's Company
Niagara Milk Cooperative, Inc.
Northwest Dairy Association
Prairie Farms Dairy, Inc.
St. Albans Cooperative Creamery, Inc.
Scioto County Co-op Milk Producers' Assn.
Select Milk Producers, Inc.
Southeast Milk, Inc.
Swiss Valley Farms, Co.
Tillamook County Creamery Assn.
United Dairymen of Arizona
Upstate Farms Cooperative Inc.
Zia Milk Producers

August 1, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket No. 2005N-0178

Dear Sir/Madam:

The following comments are being submitted on behalf of the National Milk Producers Federation (NMPF) to FDA's Notice; Agency Information Collection Activities; Proposed Collection; Comment Request; Regulations Under the Federal Import Milk Act (Docket No. 2005N-0178). NMPF, headquartered in Arlington, VA, develops and carries out policies that advance the well-being of U.S. dairy producers and the cooperatives they collectively own. The members of NMPF's 33 cooperatives produce the majority of the U.S. milk supply, making NMPF the voice of 50,000 dairy producers on Capitol Hill and with government agencies. NMPF member cooperatives also manufacture a number of dairy products regulated by FDA, including milk, cheese, ice cream, and butter, so the Federal Import Milk Act regulations are of great interest to NMPF.

Specifically, FDA requested comments on four topics relative to six forms for reporting and recordkeeping requirements in implementing the Federal Import Milk Act (FIMA). NMPF has reviewed each document and will provide comment on each document for each of the four topics for which comments were requested.

(1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility:

Form	NMPF Comment
FDA 1815	In lieu of Forms FDA 1994 and 1995, collection of information from Form 1815 is necessary for FDA to ensure the safety of imported milk or cream is produced by healthy dairy cows free from tuberculosis (TB). Tuberculosis (caused by <i>Mycobacterium bovis</i> , <i>M. avium</i> , and <i>M. tuberculosis</i>) is a contagious disease of both dairy cattle and

	<p>humans. Since 1917, the U.S. Department of Agriculture in conjunction with State animal health agencies and livestock producers has nearly eradicated bovine TB from the U.S livestock population through the Cooperative State-Federal Tuberculosis Eradication Program. Certification of TB status under Form FDA 1815 should be consistent with APHIS guidelines published in the "Bovine Tuberculosis Eradication Uniform Methods and Rules, Effective January 1, 2005" (APHIS 91-45-011).</p> <p>Brucellosis (caused by <i>Brucella</i>) is a contagious disease of both dairy cattle and humans. Since 1934, the U.S. Department of Agriculture in conjunction with State animal health agencies and livestock producers has nearly eradicated bovine brucellosis (48 States certified brucellosis free 9 CFR 78.43) from the U.S. livestock population through the Cooperative State-Federal Brucellosis Eradication Program. Certification of healthy dairy cows under Form FDA 1815 should include indication of brucellosis-free status and should be consistent with APHIS guidelines published in the "Brucellosis Eradication: Uniform Methods and Rules, Effective October 1, 2003" (APHIS 91-45-013).</p>
FDA 1993	This form is necessary and provides practical information for FDA's function under the Federal Import Milk Act.
FDA 1994	This form is necessary and provides practical information for FDA's function under the Federal Import Milk Act. Certification of TB status under Form FDA 1994 should be consistent with APHIS guidelines published in the "Bovine Tuberculosis Eradication Uniform Methods and Rules, Effective January 1, 2005" (APHIS 91-45-011).
FDA 1995	This form is necessary and provides practical information for FDA's function under the Federal Import Milk Act. Certification of health status under Form FDA 1995 should include indication of brucellosis-free status and should be consistent with APHIS guidelines published in the "Brucellosis Eradication: Uniform Methods and Rules, Effective October 1, 2003" (APHIS 91-45-013).
FDA 1996	A "Dairy Farm Sanitation Report" form is necessary for FDA's function under the Federal Import Milk Act. As rendered, Form FDA 1996 does not provide practical information for FDA's function under the Federal Import Milk Act. The Grade "A" Pasteurized Milk Ordinance (2003 Revision FDA) is incorporated by reference in Federal specifications for procurement of milk and milk products and serves as the national standard for milk sanitation. Form FDA 2359a is utilized to ensure milk sanitation standards are met at the farm level. Form FDA 1996 should be made consistent with Form FDA 2359a to ensure milk sanitation

	standards are appropriate at dairy farms from which milk or cream is imported under the Federal Import Milk Act.
FDA 1997	A "Score Card for Sanitary Inspection of Milk Plants" form is necessary for FDA's function under the Federal Import Milk Act. As rendered, Form FDA 1997 does not provide practical information for FDA's function under the Federal Import Milk Act. The Grade "A" Pasteurized Milk Ordinance (2003 Revision FDA) is incorporated by reference in Federal specifications for procurement of milk and milk products and serves as the national standard for milk sanitation. Form FDA 2359 is utilized to ensure milk sanitation standards are met at the milk processing facilities. Form FDA 1997 should be made consistent with Form FDA 2359 to ensure milk sanitation standards are appropriate at milk processing facilities from which milk or cream is imported under the Federal Import Milk Act.

(2) The accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used:

FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used, appear reasonable and appropriate based on FDA's rationale and previous years FIMA permit activity.

(3) Ways to enhance the quality, utility, and clarity of the information to be collected:

Form	NMPF Comment
FDA 1815	The utility and clarity of the information collected would be enhanced by indicating information to be contained in the attached reports. As NMPF understands the intent of this form, the attached reports should indicate the health status (including brucellosis status) and tuberculin status for each animal from which milk or cream will be imported. NMPF suggests that an example report indicating health and tuberculin status for each animal in the herd from which milk or cream will be imported be included as a guide with Form FDA 1815.
FDA 1993	NMPF has no additional comments to enhance the quality, utility, and clarity of the information to be collected on this form.
FDA 1994	NMPF has no additional comments to enhance the quality, utility, and clarity of the information to be collected on this form.
FDA 1995	Certification of health status under Form FDA 1995 should include indication of brucellosis-free status and should be consistent with APHIS guidelines published in the "Brucellosis Eradication: Uniform Methods and Rules, Effective October 1, 2003" (APHIS 91-45-013).

FDA 1996	As rendered, Form FDA 1996 does not provide practical information for FDA's function under the Federal Import Milk Act. The Grade "A" Pasteurized Milk Ordinance (2003 Revision FDA) is incorporated by reference in Federal specifications for procurement of milk and milk products and serves as the national standard for milk sanitation. Form FDA 2359a is utilized to ensure milk sanitation standards are met at the farm level. Form FDA 1996 should be made consistent with Form FDA 2359a to ensure milk sanitation standards are appropriate at dairy farms from which milk or cream is imported under the Federal Import Milk Act.
FDA 1997	As rendered, Form FDA 1997 does not provide practical information for FDA's function under the Federal Import Milk Act. The Grade "A" Pasteurized Milk Ordinance (2003 Revision FDA) is incorporated by reference in Federal specifications for procurement of milk and milk products and serves as the national standard for milk sanitation. Form FDA 2359 is utilized to ensure milk sanitation standards are met at the milk processing facilities. Form FDA 1997 should be made consistent with Form FDA 2359 to ensure milk sanitation standards are appropriate at milk processing facilities from which milk or cream is imported under the Federal Import Milk Act.

(4) Ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology:

At this time, NMPF is opposed to electronic submission of these documents utilizing an electronic signature unless submitted in accordance with 21CFR Part 11 including identification in public docket No. 92S-0251 as a type of submission that FDA accepts in electronic format.

NMPF has additional comments on the Federal Import Milk Act (FIMA) and associated Compliance Policy Guide (CPG) requirements which are out of date. U.S. producers and processors must meet stringent requirements under the *Pasteurized Milk Ordinance* (Grade "A" Pasteurized Milk Ordinance (2003 Revision FDA)). These requirements exceed those that are required under the FIMA. The plant sanitation scores, microbiological test requirements, and temperature limits are much too high in the FIMA. In addition, there is no somatic cell count limit, animal drug residue testing, coliform count, or phosphatase testing requirement in the FIMA. These requirements should be updated to reflect the same requirements that the U.S. industry must meet and to adequately protect consumers. Specifically, the following changes are needed to make the FIMA consistent with the U.S. domestic requirements:

1. Add a requirement for Brucellosis-free determination. Currently, there is no requirement for a determination as to the brucellosis status of animals, but the U.S. regulations require that milk come from healthy cows with a brucellosis and tuberculosis determination annually.
2. Raise the sanitation score to ≥ 90 . In addition, the inspection sheet used by the foreign country must be similar to what is used domestically. The current requirements are for a score of 50 out of 100 and the score sheet is not specifically mentioned. U.S. producers and processors must score 90 out of 100 on a specific score sheet.
3. A FIMA permit is issued by the U.S. upon review of records and a new permit is required each year. Inspections must be required each year, rather than relying on a previous year's data to be used on a new permit. The FIMA regulations do not specifically state an inspection time-frame.
4. Change raw milk bacteria count to 300,000/ml for commingled milk and 100,000/ml for individual producers. This will make the FIMA requirements identical to the U.S. Grade "A" requirements.
5. Add a Somatic Cell Count (SCC) standard of 750,000/ml. The FIMA currently does not have a SCC requirement, but U.S. producers must meet the 750,000/ml level.
6. Change raw cream bacteria count to 300,000/ml for commingled milk and 100,000/ml for individual producers for the reasons stated in point 4 above.
7. Add an animal drug testing requirement that is identical to that in the U.S. In addition, add a requirement that milk be tested for any animal drugs not approved for use in lactating animals that are approved in the exporting country. The FIMA does not have any requirement for animal drug residue testing of tankers whereas the U.S. program is very specific and stringent. Also, other countries allow for some animal drugs to be used in lactating animals that the U.S. has specifically prohibited. Milk should be screened for these drugs prior to it entering the U.S.
8. Change pasteurized milk Standard Plate Count to 20,000/ml. The FIMA currently has a requirement of 100,000/ml, which is much higher than the U.S. level for fluid milk.
9. Add pasteurized milk Coliform Count standard of 10/ml. There is no requirement for a coliform count on products under the FIMA.
10. Change pasteurized cream Standard Plate Count to 20,000/ml. The FIMA requirement is 500,000/ml, which is inconsistent with the U.S. requirements.
11. Add pasteurized cream Coliform Count standard of 10/ml. There is no requirement for a coliform count on products under the FIMA.
12. Change pasteurized product temperature requirement to 7°C. Finished products in the US must be kept at or below 7°C whereas the requirement in the FIMA is 10°C.
13. Add a phosphatase testing requirement. There are currently no phosphatase test requirements under the FIMA, but the U.S. has a specific test requirement.

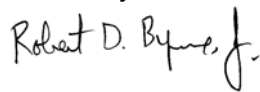
NMPF does not agree with FDA's intention to not subject some products to the FIMA permit requirement. The FIMA specifically addresses milk and cream. Some of the dairy products exempted in the CPG fall into the milk and cream category. Sour cream, cultured milk, yogurt, eggnog, acidified milk, dried milk, nonfat dry milk, fortified nonfat dry milk are all milk and cream products. Many of these have standards of identity that are contained in 21 CFR 131 – Milk and Cream. It is clear the FDA considers these to be in the Milk and Cream category. FDA has not provided any rationale for exempting these products from FIMA permit requirements. If these products are to be provided to U.S. consumers, then they should meet the same stringent regulatory requirements expected of the U.S. dairy industry, regardless of where they are produced and processed.

The CPG only addresses cow's milk. Any non-bovine milk should also be required to obtain a FIMA permit.

The CGP exempts commercially sterile dairy products. This is not provided for in the FIMA and should be removed from the CPG.

Thank you for the opportunity to provide these comments. If you have any questions or need additional information, please contact me.

Sincerely,

A handwritten signature in black ink that reads "Robert D. Byrne, Jr." with a stylized flourish at the end.

Robert D. Byrne, Ph.D.
Vice President, Regulatory Affairs